

CLAIMS

1. An oral dietary supplement acting by synergy between two bioactive component substances called a component 1 and a component 2.
2. Said component 1 may be a substance comprising:
 - a. at least one selected from the group consisting of acetyl-L-carnitine, any acylated ester of L-carnitine having an acyl chain of two to six carbon length, and pharmacological acceptable salts and derivatives thereof and mixtures thereof, and
 - b.. a pharmacological appropriate dose over the range of 10 milligrams to 20 grams.
3. Said component 2 may be a substance comprising:
 - a. at least one selected from the group consisting of L-ornithine, L-arginine, L-lysine, L-histidine, L-phenylalanine, L-leucine, L-valine, L-methionine, L-threonine, putrescine, spermidine, and pharmacological acceptable salts and derivatives thereof and mixtures thereof, and
 - b. a pharmacological appropriate dose over the range of 1 milligram to 10 grams.
4. Various pharmacological dosages of the component 1 and the component 2 may be administered by techniques comprising:
 - a. any appropriate physiological formulation including both solid and liquid formulations and mixtures thereof, and
 - b. any physiologically appropriate method of delivery of an oral dietary supplement, and
 - c. separate oral ingestion of the component 1 and the component 2 at approximately the same time, and
 - d. oral ingestion of a mixture of the component 1 and the component 2 as a single formulation.
5. Ingestion of the component 1 and the component 2 must be preceded by a fast of approximately 3 to 4 hours.
6. A method for augmenting the release of growth hormone in humans by the ingestion of the component 1 and the component 2 for the treatment of conditions and disorders selected from the group consisting of aging decline in GH release, obesity, insufficient GH release in the case of pathology and surgery, emergency needs for prolonged awakesness and physical strength, augmenting the function of

the hypothalamus, augmenting the energy production system, augmenting the immune system, augmenting the neurological system, augmenting the general anabolic conditioning of the body, improvement in the circadian rhythm entraining system, exercise related GH release, and premenopausal estrogen spike driven GH release in women.

7. The method claim 6, wherein appropriate pharmacological dose of the component 1 is 500 milligrams and the component 2 dose is 20 to 50 milligrams administered within 1 hour of night time sleep.
8. The method in claim 6, wherein appropriate pharmacological dose of the component 1 is 500 milligrams and the component 2 dose is 20 to 50 milligrams administered 1 hour before extremely vigorous exercise and 1 hour before the large pulsatile estrogen release of premenopausal women.
9. A method for augmenting the growth of immature domestic animals by oral ingestion administration of the component 1 and the component 2 within one hour of night time sleep.
10. The method claim 8, wherein the appropriate pharmacological dose of the component 1 is the product of multiplying 8 milligrams by the numerical value of the animal weight in kilograms and the component 2 dose is a range of 1 to 4 milligrams multiplied by the numerical weight of the animal in kilograms.

US PATENT DOCUMENTS

US Patent No.	DATE	NAME	(optional) Class/SubCLASS
5855920	Jan. 1999	Chein	424/568
4411890	Oct., 1983	Momany	514/17
5576351	Nov., 1996	Yoshimura et al.	514/565
6166077	Dec., 2000	De Simone	514/556
5240961	Aug., 1993	Shug	514/556
5817329	Oct., 1998	Gardiner	424/439

Foreign Patent Documents

WO9959543-A	1999.11.25	Ma
WO 97/06803	27.02.1997	Dodge
WO9640105-A	96.12.19	van Cauter
WO9744042-A	97.11.27	van Cauter
WO0021526-A	1998.10.09	Cavazza
WO0011968-A	1999.08.19	Cavazza
WO0028986-A	2000.05.25	Cavazza
WO9801128	1998.01.15	Mendes
WO 98/44793	15.10.1998	Grant
WO 00/64283	27.04.2000	White

OTHER REFERENCES CITED

1. Kojima M., Hosoda H., Date Y., Makazato M., Matsuo H., Kangawa K. (1999) Ghrelin is a growth-hormone-releasing acylated peptide from the stomach. *Nature* 402:656-660
2. van Coevorden A., Mockel J., Laurent E., Kerkhofs M., L'Hermite-Baleriaux M., Decoster C., Neve P., van Cauter E. (1991) Neuroendocrine rhythms and sleep in aging men. *Am J Physiol* 260:E651-E661
3. Mendelson W.B., Lantigua R.A., Wyatt R.J., Gillin C., Jacobs L.S. (1981) Piperidine Enhances Sleep-Related and Insulin-Induced Growth Hormone Secretion: Further Evidence of a Cholinergic Secretory Mechanism. *J Clin Endocrinol Metab* 52:409-415
4. van Cauter E, FW Turek 1995 Endocrine and Other Biological Rhythms. In: DeGroot LJ (eds) *Endocrinology* 3rd Ed. Vol 3. W. B. Saunders Co., Philadelphia, pp 2487-2548
5. Muller EE 1995 Role of Neurotransmitters and Neuromodulators in the Control of Anterior Pituitary Hormone Secretion. In: DeGroot LJ (eds) *Endocrinology*, 3rd Edition, Vol.I. pp 178-191
6. Wass JA, M Besser 1995 Tests of Pituitary Function. In: DeGroot LJ (eds) *Endocrinology* 3rd Ed. Vol. 1. W.B. Saunders Co., Philadelphia, pp 487-496
7. Parker M.L., hammond J.M., Daughaday W.H. (1967) The Arginine Provocative Test: An Aid in the Diagnosis of Hypsomatotropism. *J Clin Endocrinol Metab* 27:1129-1136
8. Corpas E., Blackman M.R., Robertson R., Scholfield D., Harman S.M. (1993) Oral Arginine-Lysine Does not Increase Growth Hormone or Insulin-like Growth Factor-I in Old Men. *J Gerontol* 48:M128-M133
9. Chin M.-Y., Kreutzer R.A. (1992) Acute Poisoning from g-Hydroxybutyrate in California. *W J Med* 156:380-384

10. Parr T. (1996) Insulin Exposure Controls the Rate of Mammalian Aging. *Mech Ageing Dev* 88:75-82
11. Parr T. (1997) Insulin Exposure and Aging Theory. *Gerontology* 43:182-200
12. Parr T. (1999) Insulin Exposure and Unifying Aging. *Gerontology* 45:121-135
13. Parr T.B. (2001) A New Technique to Elevate of Night Time Growth Hormone Release and a Potential Growth Hormone Feedback Control Loop. *Med Hypotheses* 56:610-613
14. Paradies G., Ruggiero F.M., Petrosillo G., Gadaleta M.N., Quagliarello E. (1994) The Effect of Aging and Acetyl-L-carnitine on the Function and on the Lipid Composition of Rat Heart Mitochondria. *Ann. N. Y. Acad. Sci.* 717: 233-243
15. Buttgerit F., Brand M.D. (1995) A hierarchy of ATP-consuming processes in mammalian cells. *Biochem J* 312:163-167
16. Castorina M., Ferraris L. (1994) Acetyl-L-carnitine affects aged brain receptor system in rodents. *Life Sci* 54:1205-1214
17. Ranke MB 1995 Growth Hormone Insufficiency: Clinical Features, Diagnosis, and Therapy. In: DeGroot LJ (eds) *Endocrinology* 3 rd Ed.. W. B. Saunders Co., Philadelphia, pp
18. Besset A., Bonardet A., Roundouin G., Descommes B., Passouant P. (1982) Increase in sleep related GH and Prl secretion after chronic arginine aspartate administration in man. *Acta-Endocrinol* 99:18-23
19. Spagnoli A., Lucca U., Menasce G., Bandera L., Cizza G., Forloni G., Tettamanti M., Frattura L., Tiraboschi P., Comelli M., Senin U., Longo A., Petrini A., Brambilla G., Belloni A., Negri C., Cavazzuti F., Salsi A., Calogero P., Parma E., Stramba-Bidiale M., Vitali S., Andreoni G., Inzoli M.R., Santus G., Caregnato R., Peruzza M., Favaretto M., Bozeglav C., Alberoni M., Ed Leo D., Serraiotto L., Baiocchi A., Sciccia S., Culotta P., Ieracitano D. (1991) Long -term acetyl-L-carnitine treatment in Alzheimer's disease. *Neurology* 41:1726-1732
20. Bowman B.A. (1992) Acetyl-carnitine and Alzheimer's disease. *Nutr Rev* 50:142-144
21. Pettegrew J.W., Klunk W.E., Panchalingam K., Kanfer J.N., McClure R.J. (1995) Clinical and neurochemical effects of acetyl-L-carnitine in Alzheimer's disease. *Neurobiol Aging* 16:1-4
22. Goa K.L., Brogden R.N. (1987) L-Carnitine A Preliminary Review of its Pharmacokinetics, and its Therapeutic use in Ischemic Cardiac Diseases and Primary and Secondary Carnitine Deficiencies in Relationship to its Role in Fatty Acid Metabolism. *Drugs* 34:1-24
23. Varanasi R.V., Saltzman J.R. (1995) Ornithine Oxoglutarate Therapy Improves Nutrition Status. *Nutr Rev* 53:96-97
24. Tabor H., Tabor C.W., Rosenthal S.M. (1961) The Biochemistry of the Polyamines: Spermidine and Spermine. *Annu Rev Biochem* 30:579-605
25. Cynober L. (1994) Can arginine and ornithine support gut functions? *Gut* 35:S42-S45

Disclosure Document Reference

(NOT APPLICABLE)